



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

P

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

EXAMINER

ART UNIT	PAPER NUMBER
----------	--------------

14

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/257,585

Applicant(s)

LEONG ET AL.

Examiner

Amy Nelson

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-11, 13-17, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-11, 13-17, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

15) ☐ Information

Notice of Patent is a test PTO-836

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

Information Summary, PTO-1449, is a test PTO-836

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other

Art Unit: 1638

DETAILED ACTION

Specification

1. The amendment filed 4/25/01 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

At Claims 7 and 14, line 1, the recitation of "non-mammalian" is not supported by the original specification as filed. It is not clear that Applicant ever intended to exclude mammalian cells, and to encompass only the subset of cells other than mammalian cells.

At Claim 11, the recitation of specific nucleotide positions (*e.g.* 358 and 495) is not supported by the specification as filed. No support for the specifically claimed positions can be found in the specification, and Applicant has not pointed to specific support for the amendments in the response filed 4/20/01.

Applicant is required to cancel the new matter in the reply to this Office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

Art Unit: 1638

make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 7 and 11-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

At Claims 7 and 14, line 1, the recitation of "non-mammalian" is not supported by the original specification as filed. It is not clear that Applicant ever intended to exclude mammalian cells, and to encompass only the subset of cells other than mammalian cells. Hence, the claim comprises new matter.

At Claim 11, the recitation of specific nucleotide positions (*e.g.* 358 and 495) is not supported by the specification as filed. No support for the specifically claimed positions can be found in the specification, and Applicant has not pointed to specific support for the amendments in the response filed 4/20/01.

4. Claims 1-11, 13-17, 25 and 26 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Official action mailed 9/7/00. Applicant's arguments filed 4/20/01

Art Unit: 1638

Applicant asserts that Applicant need not describe *ipsis verbis* the claimed subject matter, provided Applicant's description allows one of ordinary skill in the art to recognize the claimed invention. Applicant's disclosure of SEQ ID NO:1, in combination with procedures for hybridization, chromosome walking, and analysis of function provide sufficient evidence of Applicant's possession of the claimed subject matter (response, p. 5-6). Examiner responds that Applicant is required either to describe a representative number of the claimed genus of nucleic acid sequences, or to describe structural motifs that are common to members of the claimed genus, and hence would allow one of ordinary skill in the art to recognize other nucleic acid sequences of the claimed genus. Applicant has done neither, and hence it is unclear from the instant specification that Applicant was in possession of the invention as broadly claimed. Applicant's discussion of procedures for identification and isolation of related nucleic acid sequences is irrelevant to a written description rejection, but rather pertains only to an enablement rejection.

5. Claims 1-11, 13-17, 25 and 26 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to an isolated nucleic acid molecule encoding SEQ ID NO:4 (ORF 3), as well as transformed host cells and transgenic plants comprising said nucleic acid molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

Art Unit: 1638

record as set forth in the last Official action mailed 9/7/00. Applicant's arguments filed 4/20/01 have been fully considered but they are not persuasive.

Applicant asserts that the specification is enabling for the claims as amended. Specifically, one of skill in the art would know how to isolate a segment of chromosome 1 of *Magnaporthe grisea* of approximately 1 kb, and to determine if said segment confers rice cultivar CO39-specific avirulence to fungal plant pathogens (response, p. 7). Examiner responds that Applicant has only provided guidance for the fragment of SEQ ID NO:1 that encodes SEQ ID NO:4. Applicant does not provide guidance for isolation of other fragments of chromosome 1 that similarly confer rice cultivar CO39-specific avirulence to fungal plant pathogens. In fact, Applicant's successful isolation of the sequence of SEQ ID NO:1 is the result of extensive laborious investigation encompassing map-based cloning and chromosome walking. Applicant's suggestion that other isolated DNAs could be tested for their ability to confer CO39-specific avirulence is merely an invitation to experiment. Applicant has not provided detailed guidance for isolation of other fragments of chromosome 1, and hence the instant claims should be limited in scope to the fragment of SEQ ID NO:1 that encodes the amino acid sequence of SEQ ID NO:4 (ORF3)

Applicant argues that in that the amended claims are now limited to non-mammalian cells, the instant claims are enabled. Insect cell transformation, for example, was well known in the art at the time of Applicant's invention, as evidenced by the attached pages of the Clontech catalog (response, p. 7-8). Examiner responds that the amended claims still encompass other types of cells

Art Unit: 1638

response, and hence could not be considered. However, even though methods for transformation of insect cells and other cell types were known in the art, it is not predictable that the disclosed fungal avirulence DNA would be successfully expressed in other cell types, particularly from distantly related organisms. Further, the amended claims still encompass cells of organisms *in vivo*. As Applicant has not provided guidance for successful introduction of the disclosed DNA in hosts other than bacterial and fungal hosts, it is submitted that the claims should be limited in scope to bacterial, fungal or plant host cells.

6. Claims 2, 6-10, 13-17, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is in part repeated for the reasons of record as set forth in the last Official action mailed 9/7/00, and is in part due to Applicant's amendments to the claims. Applicant's arguments filed 4/20/01 have been fully considered but they are not persuasive.

Claim 2, in its recitation of "60% identical to SEQ ID NO:1" followed by the recitation of hybridization conditions is indefinite. Because hybridization conditions are experimental and hence are subject to variability in results, the recitation of hybridization conditions is a broader range limitation than the recitation of percent identity. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is

Art Unit: 1638

the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the claim recites the broad limitation of the formula for calculating appropriate hybridization conditions, and the claim also recites "60% identical to SEQ ID NO:1" which is the narrower statement of the range/limitation.

Claims 6 and 13 are indefinite because a vector is a circular piece of DNA, and hence it is not known how a recombinant DNA can comprise both a vector and another nucleic acid molecule, and how the vector and nucleic acid molecule are attached to one another. Clarification is required. Applicant asserts that, as defined in the enclosed Singer and Berg reference, a vector can encompass any extrachromosomal small genome, including phages and viruses. Not all phages and viruses are circular and form (response, p. 8-9). Examiner responds that the Singer and Berg reference was missing from the response filed 4/20/01, and hence could not be considered. The instant specification describes only viral and plasmid vectors (specification, p. 9, lines 16-17). Also, it is well known to those of skill in the art that only circular DNA molecules are efficiently

Art Unit: 1638

form. Hence, for all practical purposes, particularly for transporting a DNA of more than 1 kb, the instant claims to a "vector" encompass only circular DNAs. It is recommended that the claim be amended to recite --A vector comprising a recombinant DNA molecule comprising the nucleic acid molecule of Claim 1-- to more appropriately claim the intended subject matter.

At Claim 11, line 18, the phrase "high stringency" is indefinite because "high" is a relative term and hence it is not clear what is encompassed by the phrase. Appropriate correction is required to clarify the metes and bounds of the claimed invention.

Claim 25, line 2, the name "*AVRI-CO39*" is indefinite given that a name does not clearly identify the claimed gene, and does not set forth the metes and bounds of the claimed invention. The sole designation of a gene by its name or number is arbitrary and creates ambiguity in the claims. For example, the gene disclosed in this application could be designated by some other arbitrary means, or the assignment of the name could be arbitrarily changed to designate another gene. If either event occurs, one's ability to determine the metes and bounds of the claim would be impaired. Since the name *AVRI-CO39* is not known in the art, the use of said name does not carry art recognized limitations as to the specific characteristics or essential characteristics which are associated with that denomination. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). Although Applicant amended Claim 2 to delete the phrase in the response filed 4/20/01, Applicant made no such amendment to Claim 25.

Art Unit: 1638

Claim Rejections - 35 USC § 102

7. Claims 11, and 13-16 remain rejected under 35 U.S.C. 102(b) as being anticipated by Shimizu *et al.* (Infect. Immun. 59: 137-142, 1991). This rejection is repeated for the reasons of record as set forth in the last Official action mailed 9/7/00. Applicant's arguments filed 4/20/01 have been fully considered but they are not persuasive.

Applicant asserts that, as amended, the claims no longer recite "or part of." Hence, the claims are not anticipated by the Shimizu reference (response, p. 11). Examiner responds that in view of the indefiniteness of the claim limitation "high stringency," as discussed above, the claims still read on the prior art reference. Hence, the rejection is maintained.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37


Art Unit: 1638

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy J. Nelson whose telephone number is (703) 306-3218. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application, or if the examiner cannot be reached as indicated above, should be directed to the legal analyst, Yolanda Vines, whose telephone number is (703) 305-2365.



AMY J. NELSON, PH.D
PRIMARY EXAMINER

Amy J. Nelson, Ph.D.

May 28, 2001